

Amendment to the Claims:

This listing of claims will replace all prior versions and listings of claims in the application:

Listing of Claims:

Claim 1 (previously presented): A method of sterilizing a balloon susceptible to degradation by ionizing radiation, comprising

(a) packaging said balloon in a first sealed interior space of a pouch capable of providing a barrier to atmospheric oxygen, wherein said pouch includes a first layer including a plastics-coated foil, a second layer having a porosity of 18-240 seconds by the Gurley porosimeter test, and a third layer including a plastics-coated foil, wherein the second layer is disposed between the first layer and the third layer;

(b) placing an oxygen absorber in a second sealed interior space of the pouch, wherein said second sealed interior space is formed by a seal line formed in the layers of said pouch;

(c) exposing said balloon enclosed in said pouch to a nitrogen gas flush sufficient to reduce the oxygen content within said pouch to less than about 10%; and

(d) exposing said balloon and said oxygen absorber enclosed in said pouch to ionizing radiation, wherein said ionizing radiation is either gamma radiation or electron beam radiation at a dose of no greater than about 100 kGy.

Claim 2 (original): A method according to claim 1, wherein said balloon is part of a balloon dilatation catheter.

Claim 3 (original): A method according to claims 1 or 2, wherein said balloon is manufactured from one or more block polymers selected from the group consisting of polyester block copolymers, polyamide block copolymers, polyurethane block copolymers, a mixture of nylon and polyamide block copolymers, and a mixture of polyethylene terephthalate and polyester block copolymers.

Claim 4 (canceled).

Claim 5 (currently amended): A method according to claim 1, wherein said first layer comprises 12 μ PET, 25.4 μ WPE/Foil/Adhesive and 50 μ ~~Clear EZ PEEL@~~ clear, fully coextruded, nylon-core top web system material, said second layer comprises ~~2FS Uncoated TYVEK@~~ uncoated thin flexible opaque sheet material having multiple spun woven extruded polyethylene strands forming a complex system of microscopic porous channel which provides a tortuous path therethrough, and said third layer comprises 12 μ PET, 25.4 μ WPE/Foil/Adhesive and 50 μ ~~Clear EZ PEEL@~~ clear, fully coextruded, nylon-core top web system material.

Claim 6 (canceled).

Claim 7 (original): A method according to claim 1, wherein said oxygen content is between about 5% and about 10%.

Claim 8 (original): A method according to claim 1, wherein said oxygen content is less than about 1%.

Claims 9 and 10 (canceled).

Claim 11 (previously presented): A method of sterilizing a balloon susceptible to degradation by ionizing radiation, comprising:

- (a) packaging said balloon in a first sealed interior space of a pouch capable of providing a barrier to atmospheric oxygen, wherein said pouch includes a first layer including a plastics-coated foil, a second layer having a porosity of 18-240 seconds by the Gurley porosimeter test, and a third layer including a plastics-coated foil, wherein the second layer is disposed between the first layer and the third layer;
- (b) placing an oxygen absorber in a second sealed interior space of the pouch wherein said second sealed interior space is formed by a seal line formed in the layers of said pouch;
- (c) exposing said balloon enclosed in said pouch to a nitrogen gas flush sufficient to reduce the oxygen content in said pouch; and

(d) exposing said balloon and said oxygen absorber enclosed in said pouch to ionizing radiation, while avoiding the concomitant degradation associated with sterilization at atmospheric oxygen levels.

Claim 12 (original): A method according to claim 11, wherein said balloon is part of a balloon dilatation catheter.

Claim 13 (original): A method according to claims 11 or 12, wherein said balloon is manufactured from one or more block polymers selected from the group consisting of polyester block copolymers, polyamide block copolymers, polyurethane block copolymers, a mixture of nylon and polyamide block copolymers, and a mixture of polyethylene terephthalate and polyester block copolymers.

Claim 14 (canceled).

Claim 15 (currently amended): A method according to claim 11, wherein said first layer comprises 12 μ PET, 25.4 μ WPE/Foil/Adhesive and 50 μ ~~Clear EZ PEEL®~~ clear, fully coextruded, nylon-core top web system material, said second layer comprises ~~2FS Uncoated TYVEK®~~ uncoated thin flexible opaque sheet material having multiple spun woven extruded polyethylene strands forming a complex system of microscopic porous channel which provides a tortuous path therethrough, and said third layer comprises 12 μ PET, 25.4 μ WPE/Foil/Adhesive and 50 μ ~~Clear EZ PEEL®~~ clear, fully coextruded, nylon-core top web system material.

Claim 16 (canceled).

Claim 17 (original): A method according to claim 11, wherein said ionizing radiation is either gamma irradiation or electron beam irradiation.

Claim 18 (original): A method according to claim 17, wherein said gamma irradiation is the administered at a dose rate of about 1 kGy/hrs to about 10 kGy/hrs.

Claim 19 (original): A method according to claim 17, wherein said electron beam irradiation is administered at a dose rate of no greater than about 20 kGy/s.

Claim 20 (original): A method according to claim 11, wherein said nitrogen gas flush is administered at a pressure of less than about 10 psi and said oxygen content is less than about 10%.

Claim 21 (original): A method according to claim 20, wherein said oxygen content is between about 5% and about 10%.

Claim 22 (original): A method according to claim 20, wherein said oxygen content is less than about 1%.

Claims 23-26 (canceled).

Claim 27 (withdrawn): A balloon and packaging system comprising:
a pouch having a first sealed interior space and a second sealed interior space, wherein said pouch includes a first layer including a plastics-coated foil, a second layer having a porosity of 18-240 seconds by the Gurley porosimeter test, and a third layer including a plastics-coated foil, wherein the second layer is disposed between the first layer and the third layer, and wherein said first sealed interior space and second sealed interior space are separated by a seal line formed in the layers of said pouch;
a balloon disposed in the first sealed interior space; and
an oxygen absorber disposed in the second sealed interior space.

Claim 28 (withdrawn): The system of claim 27, wherein said balloon is part of a balloon dilatation catheter.

Claim 29 (withdrawn): The system of claim 27, wherein said balloon comprises one or more block polymers selected from the group consisting of polyester block copolymers, polyamide block copolymers, polyurethane block copolymers, a mixture of nylon and polyamide block copolymers, and a mixture of polyethylene terephthalate and polyester block copolymers.

Claim 30 (withdrawn - currently amended): The system of claim 27, wherein said first layer comprises 12 μ PET, 25.4 μ WPE/Foil/Adhesive and 50 μ ~~Clear EZ PEEL®~~ clear, fully coextruded, nylon-core top web system material, said second layer comprises ~~2FS Uncoated TYVEK®~~ uncoated thin flexible opaque sheet material having multiple spun woven extruded polyethylene strands forming a complex system of microscopic porous channel which provides a tortuous path therethrough, and said third layer comprises 12 μ PET, 25.4 μ WPE/Foil/Adhesive and 50 μ ~~Clear EZ PEEL®~~ clear, fully coextruded, nylon-core top web system material.

Claim 31 (withdrawn): A pouch for use in sterilizing a balloon, the pouch comprising:

a first layer including a plastics-coated foil;

a second layer having a porosity of 18-240 seconds by the Gurley porosimeter test; and

a third layer including a plastics-coated foil, wherein the second layer is disposed between the first layer and the third layer,

wherein a seal line is formed in the layers of the pouch, said seal line dividing an interior space of the pouch into a first sealed interior space suitable for receiving the balloon and a second sealed interior space suitable for receiving an oxygen absorber.

Claim 32 (withdrawn – currently amended): The pouch of claim 31, wherein said first layer comprises 12 μ PET, 25.4 μ WPE/Foil/Adhesive and 50 μ ~~Clear EZ PEEL®~~ clear, fully coextruded, nylon-core top web system material, said second layer comprises ~~2FS Uncoated TYVEK®~~ uncoated thin flexible opaque sheet material having multiple spun woven extruded polyethylene strands forming a complex system of microscopic porous channel which provides a tortuous path therethrough, and said third layer comprises 12 μ PET, 25.4 μ WPE/Foil/Adhesive and 50 μ ~~Clear EZ PEEL®~~ clear, fully coextruded, nylon-core top web system material.